UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

PAMELA COLEMAN, **Plaintiff,** **v.** **BOSTON SCIENTIFIC CORPORATION, et al.,** **Defendants.**	**1:10-cv-01968-OWW-SKO** **MEMORANDUM DECISION REGARDING MOTION TO DISMISS FIRST AMENDED COMPLAINT (Doc.34)**

I. INTRODUCTION.

Pamela Coleman ("Plaintiff") proceeds with an action for damages against Boston Scientific Corporation ("Defendant") and various Doe Defendants. Plaintiff filed a First Amended Complaint ("FAC") on June 17, 2011. (Doc. 31).

Defendant filed a motion to dismiss the FAC on July 7, 2011. (Doc. 34). Plaintiff filed opposition to the motion to dismiss on August 1, 2011. (Doc. 39). Defendant filed a reply on August 8, 2011. (Doc. 44).

II. FACTUAL BACKGROUND.

On December 5, 2006, a physician implanted a surgical mesh device manufactured by Defendant into Plaintiff in connection with treatment of Plaintiff's stress urinary incontinence. The surgical mesh device is described as an Obtryx Transobturator Mid-Urethral

Sling System ("Mesh Device") and is designed to restore normal vaginal structure secondary to pelvic organ prolapse. Plaintiff began to experience "recurrent pelvic pain, erosions, and recurrent infection of the tissue around the mesh" subsequent to implantation of the Mesh Device. From July 2007 through January 2009, Plaintiff underwent surgery, vaginal reconstruction, and mesh removal "to correct the injuries caused by the mesh." (FAC at 8).

The FAC alleges that Defendant marketed the Mesh Device in a deceptive manner to the medical community and patients at medical conferences, hospitals, private offices, and through documents, brochures, and websites. Contrary to Defendant's representations, the Mesh Device has high failure, injury, and complication rates, fails to perform as intended, and requires frequent re-operations. Defendant withheld and underreported information about the safety of its Mesh Device. Defendants also failed to adequately research and test its Mesh Product.

III. LEGAL STANDARD.

Dismissal under Rule 12(b)(6) is appropriate where the complaint lacks sufficient facts to support a cognizable legal theory. Balistreri v. Pacifica Police Dep't, 901 F.2d 696, 699 (9th Cir.1990). To sufficiently state a claim to relief and survive a 12(b) (6) motion, the pleading "does not need detailed factual allegations" but the "[f]actual allegations must be enough to raise a right to relief above the speculative level." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). Mere "labels and conclusions" or a "formulaic recitation of the elements of a cause of action will not do." Id. Rather, there must be "enough facts to state a claim to relief that is plausible on

its face." Id. at 570. In other words, the "complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, --- U.S. ----, ----, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009) (internal quotation marks omitted).

The Ninth Circuit has summarized the governing standard, in light of Twombly and Iqbal, as follows: "In sum, for a complaint to survive a motion to dismiss, the nonconclusory factual content, and reasonable inferences from that content, must be plausibly suggestive of a claim entitling the plaintiff to relief." Moss v. U.S. Secret Serv., 572 F.3d 962, 969 (9th Cir.2009) (internal quotation marks omitted). Apart from factual insufficiency, a complaint is also subject to dismissal under Rule 12(b)(6) where it lacks a cognizable legal theory, Balistreri, 901 F.2d at 699, or where the allegations on their face "show that relief is barred" for some legal reason, Jones v. Bock, 549 U.S. 199, 215, 127 S.Ct. 910, 166 L.Ed.2d 798 (2007).

In deciding whether to grant a motion to dismiss, the court must accept as true all "well-pleaded factual allegations" in the pleading under attack. Iqbal, 129 S.Ct. at 1950. A court is not, however, "required to accept as true allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." Sprewell v. Golden State Warriors, 266 F.3d 979, 988 (9th Cir.2001). "When ruling on a Rule 12(b)(6) motion to dismiss, if a district court considers evidence outside the pleadings, it must normally convert the 12(b)(6) motion into a Rule 56 motion for summary judgment, and it must give the nonmoving party an opportunity to respond." United States v. Ritchie, 342 F.3d 903,

907 (9th Cir.2003). "A court may, however, consider certain materials-documents attached to the complaint, documents incorporated by reference in the complaint, or matters of judicial notice-without converting the motion to dismiss into a motion for summary judgment." Id. at 908.

IV. DISCUSSION.

A. Statute of Limitations

California law establishes a two-year statute of limitations for personal injury actions. Cal. Code Civ. Proc. 335.1; *e.g.*, *Mito v. Temple Recycling Center Corp.*, 187 Cal. App. 4th 276, 278-79 (Cal. Ct. App. 2011). As a general rule, a cause of action accrues "when, under the substantive law, the wrongful act is done, or the wrongful result occurs." *E.g., Unruh-Haxton v. Regents of University of California*, 162 Cal. App. 4th 343, 359 (Cal. Ct. App. 2008). "An important exception to the general rule of accrual is the 'discovery rule,' which postpones accrual of a cause of action until the plaintiff discovers, or has reason to discover, the cause of action." *Fox v. Ethicon Endo-Surgery, Inc.*, 35 Cal. 4th 797, 807) (citing *Norgart v. Upjohn Co.*, 21 Cal. 4th 383, 397 (Cal. 1999)).

A plaintiff has reason to discover a cause of action when he or she "has reason at least to suspect a factual basis for its elements." *Id.* at 808. Plaintiffs are charged with presumptive knowledge of an injury if they have " information of circumstances to put them on inquiry," or if they have "the opportunity to obtain knowledge from sources open to their investigation." *Id.* (citations and quotations omitted). However, "the rule in California is that it is not enough to commence the running of the

limitations period when the plaintiff knows of her injury and its factual cause (or physical cause)." *Clark v. Baxter Healthcare Corp.*, 83 Cal. App. 4th 1048, 1056 (Cal. Ct. App. 2000). "Rather, the plaintiff must be aware of her injury, its factual cause, and sufficient facts to put her on inquiry notice of a [wrongful] cause [of injury]." *Id.* (citing *Jolly v. Eli Lilly & Co.*, 44 Cal. 3d 1103, 1109-1114 (Cal. 1988)). The discovery rule is based on an objective standard that looks not to what the particular plaintiff actually knew but to what a reasonable inquiry would have revealed. *Mills v. Forestex Co.*, 108 Cal. App. 4th 625, 648 (Cal. Ct. App. 2003) (citation omitted); *accord Landale-Cameron Court, Inc. v. Ahonen*, 155 Cal. App. 4th 1401, 1407 (Cal. Ct. App. 2007) (citing *Mills*).

The FAC alleges that Plaintiff underwent surgery in July 2007 in order to effect vaginal reconstruction, mesh removal, and correction of "injuries caused by the mesh." (FAC at 8). Although the FAC's allegations are vague, the plain meaning of the FAC's allegation that Plaintiff "was forced to undergo revisionary surgery vaginal reconstruction, and mesh removal to correct the injuries caused by the mesh" suggests that Plaintiff was aware of sufficient facts to put her on inquiry notice in July 2007 that reconstructive surgery was necessary because the device did not perform. A reasonable person who is implanted with a medical device, which requires a second corrective surgery to remove the device and correct injuries resulting there from within a year of implantation should suspect the defectiveness of the device and conduct a reasonable inquiry and examination into the suitability of the device. *See Henderson v. Pfizer, Inc.*, 285 Fed. Appx. 370,

372 (9th Cir. 2008) (unpublished) (holding that two-year limitations period under California Code of Civil Procedure 335.1 for claim arising out of injury caused by medical device accrued at the time plaintiff required surgery to remove the device). The FAC's own allegations suggest that Plaintiff's claim is time-barred, as it was not filed within two years of Plaintiff's July 2007 surgery.[1]

Plaintiff contends she was not put on inquiry notice of her claim until publication of an FDA warning in 2008. The FDA publication discussed a range of potential risks associated with implantation of medical devices such as the Mesh Device that injured Plaintiff. Plaintiff's attempt to rely on the FDA publication is unavailing, as it did not put Plaintiff on notice of any new facts relevant to her claim. By the time of the FDA publication in 2008, at least one of the types of risks discussed in the FDA publication had already materialized for Plaintiff and required surgery in July 2007. To the extent Plaintiff understood the reason for her July 2007 surgery, she was on inquiry notice at that time. Plaintiff's conclusory averments of fraud and concealment are also unavailing. The FAC does not allege ultimate

[1] Due to the lack of detail concerning the nature of Plaintiff's 2007 surgery, it cannot be said as a matter of law that Plaintiff was on inquiry notice of her claims in 2007. For this reason, Plaintiff is given leave to amend. Because Plaintiff's FAC suggests on its face that her claims are time-barred, any amended complaint must plead facts sufficient to suggest application of the discovery rule. *See, e.g., McKelvey v. Boeing North American, Inc.*, 74 Cal. App. 4th 151, 160, 86 Cal. Rptr. 2d 645 (Cal. Ct. App. 1999) *partially superceded on other grounds as stated in Grisham v. Philip Morris U.S.A., Inc.*, 40 Cal. 4th 623, 637 n.8, 54 Cal. Rptr. 3d 735, 151 P.3d 1151 (Cal. Ct. App. 2007). In the context of Plaintiff's July 2007 surgery, Plaintiff must allege facts to suggest that, due to the nature of the surgery and the information Plaintiff possessed regarding the procedure, a reasonable person in Plaintiff's position would not have suspected that the Mesh Device was defective.

facts sufficient to suggest that Defendant engaged in any conduct that prevented Plaintiff from investigating the circumstances that required her to undergo surgery in July 2007.

Plaintiff will be given one last opportunity to amend her complaint to allege facts sufficient to suggest that Plaintiff's claims are not time-barred, subject to the requirements of Federal Rule of Civil Procedure 11. Plaintiff has not heeded the prior instructions of the court. Her continued disregard of the court's orders will be handled accordingly.

B. Defendant's Learned Intermediary Argument

Defendant invokes California's "learned intermediary doctrine," which imposes the duty to warn of dangers associated with a medical product on the physician, not the patient, under appropriate circumstances. *See, e.g., Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89, 98 n.5 (Cal. Ct. App. 2008) ("under the learned-intermediary doctrine Wyeth's duty to warn of risks associated with its usage runs to the physician, not the patient"). The complaint sufficiently alleges that Defendant failed to disclose material information concerning use of the Mesh Device to "Plaintiff and/or Plaintiff's healthcare providers." (FAC at 6-7). The FAC also alleges that Defendant's product literature falsely assured "Plaintiff's healthcare providers and physicians" that the Mesh Device was safe for treating Plaintiff's conditions. (Id.). The learned intermediary argument articulated in Defendant's Motion to Dismiss does not provide a basis for dismissing the FAC. The motion to dismiss on this ground is DENIED.

C. Express Warranty Claim

"As a general rule, privity of contract is a required element

of an express breach of warranty cause of action." *E.g., Fieldstone Co. v. Briggs Plumbing Products, Inc.*, 54 Cal. App. 4th 357, n.10 (Cal. Ct. App. 1997). However, privity is not an absolute requirement for express warranty claims under California law, because reliance on a seller's representations may provide the basis for an express warranty claim even absent privity. *Id.* The memorandum decision dismissing Plaintiff's original complaint provides, in pertinent part:

> Defendants' contention that privity is an element of an express warranty claim is incorrect. *E.g., Evraets*, 29 Cal. App. 4th at 857 n.4 ("privity is not a requirement for actions based upon an express warranty"); *Fieldstone Co. v. Briggs Plumbing Products, Inc.*, 54 Cal. App. 4th 357, n.10 (Cal. Ct. App. 1997) ("As a general rule, privity of contract is a required element of an express breach of warranty cause of action. However, there is an exception where plaintiff's decision to purchase the product was made in reliance on the manufacturers' written representations in labels or advertising materials.") (citations omitted). However, Plaintiffs express warranty claims must be dismissed, as the complaint does not allege facts sufficient to give rise to a plausible basis to believe that Plaintiffs relied on any representations made by Defendants. *See, e.g., id.*
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> Plaintiffs' conclusory allegations that Defendants advertised their products as safe and effective lack even general information describing such alleged conduct. As one district court has aptly noted, conclusory allegations such as those advanced by Plaintiffs are insufficient to support a plausible basis for an express warranty claim:
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> > Evraets stands as clear authority that at least at the pleading stage, California law permits a claim for breach of an express warranty to go forward under circumstances [where reliance is alleged]. That said, the complaint as presently constituted fails to allege any express warranties actually made by Stryker, except in the most general and conclusory terms. Accordingly, the claim for breach of express warranty will be denied, with leave to amend.
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> *Quatela v. Stryker Corp.*, 2010 U.S. Dist. LEXIS 133706 * 4-6 (N.D. Cal. 2010).

The FAC alleges neither privity nor reliance as the basis for Plaintiff's express warranty claim. Plaintiff's argument that she need not plead reliance in order to state a cognizable breach of express warranty claim is contrary to California law and ignores the analysis provided in the memorandum decision.[2] None of the authorities Plaintiff cites in her opposition support the erroneous proposition that reliance is not required in an express warranty action not founded on privity.

Plaintiff cites *Weinstat v. Dentsply Intern., Inc.*, 180 Cal. App. 4th 1213, 1225 (Cal. Ct. App. 2010) and *Keith v. Buchanan*, 173 Cal. App. 3d 13, 21 (Cal. Ct. App. 1985) for the proposition that reliance is not a requirement of her express warranty claim. In *Winestat* the purchasers of dental equipment sued the seller, and the express warranty claim was based on privity. *See id.* Similarly, in *Keith*, the purchaser of a boat sued the company that sold him the boat and allegedly made express warranties antecedent to the transaction. Neither *Weinstat* nor *Keith* supports Plaintiff's erroneous contention that reliance is not required where privity is absent.

Plaintiff's invocation of California Commercial Code section 2313 is unavailing, as it does not alter the requirement that reliance (or some other substitute for privity) is required for an express warranty claim against a non-selling manufacturer of a

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[2] In light of the memorandum decision, Plaintiff's counsel's argument that neither reliance nor privity is required, without so much as attempting to address the court's prior analysis, violates Federal Rule of Civil Procedure 11 and applicable standards of professional conduct. Plaintiff's disingenuous attempt to characterize the correct arguments advanced in Defendant's brief as misleading compounds counsel's breach of duty.

product. *See, e.g., Wiley v. Yihua Int'l Group*, 2009 Cal. App. Unpub. LEXIS 8880 * 13-16 (Cal. Ct. App. 2009) (unpublished).

> In *Burr v. Sherwin Williams Co.* 42 Cal.2d 682, (1954) the California Supreme Court held "[t]he general rule is that privity of contract is required in an action for breach of either express or implied warranty and that there is no privity between the original seller and a subsequent purchaser who is in no way a party to the original sale." *Id.* at p. 695; *see also Windham at Carmel Mountain Ranch Assn. v. Superior Court* 109 Cal. App. 4th 1162, 1169 (Cal. 2003) [same, quoting *Burr*]; *Arnold v. Dow Chemical Co.* 91 Cal. App. 4th 698, 720 (Cal. Ct. App. 2001) [same, quoting *Burr*]; *All West Electronics, Inc. v. M-B-W, Inc.* 64 Cal.App.4th 717, 725 (1998)[same, quoting Burr].) Burr observed that courts created exceptions to the privity rule for items such as foodstuffs (Burr, at p. 695), and after *Burr*, the exception was extended to drugs and pesticides. *See Windham at Carmel Mountain Ranch*, at p. 1169 & fn. 7 [observing these exceptions were created by courts before the establishment of the doctrine of strict liability in tort]; *Arnold v. Dow Chemical Co.*, at pp. 720-721; Fundin v. Chicago Pneumatic Tool Co. (1984) 152 Cal.App.3d 951, 956, fn. 1.) *Burr* also recognized that "[a]nother possible exception to the general rule is found in a few cases where the purchaser of a product relied on representations made by the manufacturer in labels or advertising material, and recovery from the manufacturer was allowed on the theory of express warranty without a showing of privity." (*Burr*, 42 Cal.2d at p. 696; *see also Smith v. Gates Rubber Co. Sales Division* (1965) 237 Cal.App.2d 766, 768.)
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> Since Burr, the California Supreme Court has made statements in cases broadly suggesting that courts no longer require privity in express warranty cases. (See Seely v. White Motor Co. (1965) 63 Cal.2d 9, 14 ["Since there was an express warranty to plaintiff in the purchase order, no privity of contract was required"]; Hauter, supra, 14 Cal.3d at p. 115, fn. 8 ["The fact that [plaintiff] is not in privity with defendants [*20] does not bar recovery. Privity is not required for an action based upon an express warranty"].) However, Seely and Hauter did not overrule Burr, and, unlike the case at hand, both cases involve written warranties similar to advertisements and labels where the plaintiffs saw and relied upon the written statements in purchasing the product at issue. (Seely, at p. 13 [plaintiff relied on statements in purchase order when buying a truck]; Hauter, at pp. 109, 117 [plaintiff read and relied on defendant's representation on the label of a shipping carton].) The broad language in Seely and Hauter narrows significantly when read in the context of those facts. Further, as indicated above, several cases decided after

> Seely reflect the continuing validity of Burr's privity requirement. (Windham at Carmel Mountain Ranch Assn. v. Superior Court, supra, 109 Cal.App.4th at p. 1169; Arnold v. Dow Chemical Co., supra, 91 Cal.App.4th at p. 720; All West Electronics, Inc. v. M-B-W, Inc., supra, 64 Cal.App.4th at p. 725.) We conclude plaintiffs' asserted "independent liability" theory under section 2313 is defeated by the fact they did not bargain with or directly purchase the products from Yihua, and were not in privity of contract with it.

Id.

Finally, Plaintiff's attempt to rely on California Civil Code section 1791.2 fails. Section 1791 defines the term "consumer goods" as

> any new product or part thereof that is used, bought, or leased for use primarily for personal, family, or household purposes, except for clothing and consumables. "Consumer goods" shall include new and used assistive devices sold at retail.

Cal Civ. Code. 1791(a). Assistive device is defined as:

> any instrument, apparatus, or contrivance, including any component or part thereof or accessory thereto, that is used or intended to be used, to assist an individual with a disability in the mitigation or treatment of an injury or disease or to assist or affect or replace the structure or any function of the body of an individual with a disability, except that this term does not include prescriptive lenses and other ophthalmic goods unless they are sold or dispensed to a blind person, as defined in Section 19153 of the Welfare and Institutions Code and unless they are intended to assist the limited vision of the person so disabled.

Cal. Civ. Code 1791 (p). Although the Mesh Device appears to fall within the scope of the term "assistive device," the FAC does not allege the "sale at retail" of any assistive device.

In light of Plaintiff's inability to amend her complaint to allege reliance or privity after being provided with express instructions in the Memorandum Decision, Plaintiff's express

warranty claim is DISMISSED WITH PREJUDICE.

ORDER

For the reasons stated, IT IS ORDERED:

1) Plaintiff's express warranty claim is DISMISSED WITH PREJUDICE;

2) Plaintiff's remaining claims are dismissed, without prejudice;

3) Plaintiff shall file an amended complaint within thirty days of electronic service of this decision; no further leave to amend will be given. Defendant shall respond to any amended complaint within thirty days; and

4) Defendant shall file a form of order consistent with this memorandum decision within five days of electronic service of this decision.

IT IS SO ORDERED.

Dated: August 29, 2011

/s/ Oliver W. Wanger
UNITED STATES DISTRICT JUDGE